Remarks and Arguments

Overview:

The claims are all in general directed to methods using combination catheters to form "out-of-plane" shapes. The prior art cited by the Examiner is primarily directed to pointing rather than shaping. And none of the art teaches the unexpected result—the formation of out-of-plane shapes when curved distal end portions of inner and outer elements interact—that form the basis of these claims. From two relatively simple elements—an inner element and an outer tube, Dr. Paskar (the present inventor) has developed a catheter that may be shaped into numerous shapes that in the prior art are achievable only by using a plurality of separate, pre-shaped catheters. Applicant has previously briefed this case for appeal. He hereby incorporates all those arguments for patentability herein by reference. The present response is primarily directed to the Examiner's latest variations of the previous rejections.

§ 112 Rejection:

The Examiner has rejected claims 22 and 29 under Sec. 112 for an alleged failure of the specification to describe the invention in such a way as to reasonably convey to one skilled in the relevant art that the inventor had, at the time the application was filed, possession of the claimed invention.

The present application has the same disclosure as that found in the parent application that is now U.S. patent 6,623,449. That disclosure provides as the fourth object:

"A fourth object is the provision of such a catheter which can mimic almost any catheter configuration, and can thereafter be reformed in the body to other desired shapes."

A primary goal of the present invention, therefore, is clearly stated to be the reformation of the catheter from one "desired shape" to another "desired shape".

The specification goes on to provide that whole families of these "desired shapes" can be out of plane, as shown in the following passage:

"Again, a whole family of these "out of plane" curves can be achieved as desired by the user by curving the sheath more or less and exposing more or less of the inner catheter or element. See FIG. 15B."

As anyone could plainly understand, the whole purpose of a "desired shape" in a catheter is to use that "desired shape" in a medical procedure—otherwise there is no good reason for forming the desired shape.

The § 112 rejection should be withdrawn.

Rejection of Claims 19-22 under § 102(b) as Anticipated by Ganz

Ganz et al. uses **two separate inner catheters to catheterize the two passageways.** These catheters are labeled 11a and 11b in Ganz. See col. 7, lines 24-33 for a description of inner catheter 11a, and col. 7, lines 45-57 for a description of inner catheter 11b. Element 105 is a preformed bend in inner catheter 11a. See col. 6, lines 40-57, which state:

"Figs. 6 and 7 show a catheter 11a which is identical to the catheter 11 in all respects not shown or described herein. Portions of the catheter 11a corresponding to portions of the catheter 11 are designated by corresponding reference numerals followed by the letter 'a'.

"The only difference between the catheters 11 and 11a is in the configuration of the distal end portions. Specifically, the distal end portion 47 is straight, whereas the **distal end portion 47a has** two resilient orientation bend sections 101 and 103 and **a passage-seeking bend section 105** which is also resilient. The passage-seeking bend section 105 is **configured to seek out the left anterior descending coronary artery** 107(Fig. 12). The orientation bend **sections 101 and 103 automatically orient the passage-seeking bend section 105** when the **catheter 11a is used within an angiography catheter, such as an angiography catheter 57a** (Fig. 12) which is designed for exploring the left coronary arteries." (Emphasis added)

Rather than teach rotating inner catheter 11a to obtain the configuration of Fig. 13, Ganz teaches using a completely new inner catheter 11b to create that shape. Col. 7, lines 45 to 53 states:

"Fig. 8 shows a **catheter 11b** which **is identical to the catheter 11a, except** that the **bend section 105b is displaced 180 degrees from the bend section 105.** The catheter 11b can be used with the angiography catheter 57a as shown in Fig. 13 in the same manner as described above with reference to Fig. 12. In terms of operation, the only difference is that the **bend section 105b emerges from the distal opening 65a approximately 180 degrees displaced from the bend section 105.**" (Emphasis added).

There are two different inner catheters used in Ganz—catheter 11a for use as shown in Fig. 12 and catheter 11b for use as shown in Fig. 13. Note that the quoted passage states that catheters 11a and 11b are identical except for bend sections 105 and

105b. This means that both have the orientation bend sections 101 and 103 that orient the inner catheter with respect to the outer catheter 57a. But they differ in that the bend sections 105 and 105b are basically curved in opposite directions, so that as they emerge from the outer catheter they emerge pointing in basically opposite directions.

Claim 19 is an independent claim that requires "forming the combination catheter into a shape in which the distal end of the combination catheter is disposed substantially out of the first plane for a period of time sufficient to permit medical use of at least one of the catheter tube or the inner medical element." As explained above, there is no showing that Ganz et al. provides such an out-of-plane feature. Claim 19 is allowable for this reason. Claims 20-22depend from and relate back to claim 19 and are allowable therewith. Claim 21 further requires reforming the distal end of the combination catheter into a substantially different shape. As discussed above, Ganz et al. requires a different inner catheter 11b to form the substantially different shape. The present invention is, therefore, a substantial improvement over Ganz et al. Claim 22 depends from claim 21 and further specifies that the reformed combination catheter is used in a medical procedure while the distal end of the combination catheter is in the reformed shape. Ganz et al. requires two separate inner catheters (11a and 11b) to obtain two different shapes. The present invention merely reforms the catheters already in place. The vast savings in time and expense, and the resulting improvement in patient outcomes should be apparent.

The Examiner asserts that some of the elements are found in Ganz because during removal the catheter would be reformed "in a catheterization removal medical procedure." Applicant is unaware of a "catheterization removal medical procedure" that

is recognized by anyone of any skill in this art. See affidavit of Paskar filed herewith. Perhaps, since applicant—a practicing physician—has no knowledge of such a recognized medical procedure and no reference identifying the removal of a catheter as a "medical procedure" has been presented, the Examiner could find some teaching in the art that such a "catheterization removal medical procedure" is recognized by those in the art before citing such an unknown procedure against application.

The Examiner's rejection based upon Ganz et al. is, therefore, in error.

Rejection of Claims 10-16, 24-26, 28, and 31-34 over Ganz in view of Saice (and Badger in the case of claim 13):

The Examiner states that "Applicant differs from Ganz in explicitly stating a fixing step in which the inner surgical element is fixed in an out of plane configuration."

As discussed above, the catheter in Ganz is never in an "out of plane configuration", so it would be impossible to fix it in such a configuration. The addition of the Saice reference to provide for fixing is, therefore, irrelevant since Ganz is never in an out of plane configuration, as defined in these claims.

Turning specifically to these claims, claim 10 requires a catheter tube having a distal end portion fixed in a first curve and disposing an inner medical element in the catheter tube. The claim further requires fixing the distal end portion of the inner medical element in a second curve such that the distal end of the inner medical element is disposed substantially out of the first plane for a period of time sufficient to permit medical use of at least one of the catheter tube or the inner medical element.

This out-of-plane feature is illustrated below. Fig. 15 from the present application is an elevation in which the inner medical element 35 is coming out of the plane of the

paper. Fig. 15A is a top plan view in which "P" is the plane of the paper in Fig. 15 and inner medical element 35 is clearly illustrated as coming out of the plane P. Fig. 15B is a perspective line drawing showing various out-of-plane shapes achievable by the present invention. It should be appreciated that out-of-plane shapes are useful not because they point in particular directions (a simpler shape pointing in the same direction can always be found), but because those shapes provide an "anchoring" or "wedging" effect that maintains the combination catheter in a desired position in the body. As will appear, the prior art cited against these "out-of-plane" claims are directed to aiming, not shaping.

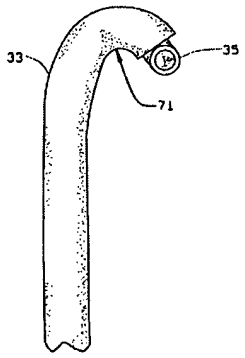


FIG. 15

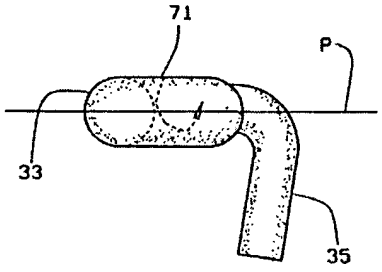


FIG. 15A

FIG. 15B

Front Elevation **Top Plan** **Line Drawings of Out-of-Plane Shapes**

In these figures, the portion of the catheter tube adjacent the distal end of the catheter tube defines a distal end portion of the catheter tube 33, said distal end portion assuming and maintaining a curved configuration such that the distal end portion of the catheter tube is disposed substantially in a first plane. The first plane P is illustrated in Fig. 15A of the present application, above. Note that the distal end portion of catheter tube 33 is disposed in plane P, while the distal end portion of inner element 35 is disposed substantially out of plane P.

In these figures, the inner medical element 35 is disposed in the lumen of the catheter tube, said inner medical element has a distal end portion (the distal end portion of the inner medical element is illustrated in Fig. 15A) disposed substantially in a second plane (which is clearly shown in Fig. 15A). The inner medical element 35 is also specified as being positioned with respect to the catheter tube 33 such that the first plane P is disposed at a significant angle with respect to the second plane.

When the inner catheter or element is fixed at some intermediate rotational position, such as ninety degrees, with respect to the distal end portion of the outer tube, as illustrated above, the out-of-plane shapes of the present invention result. The curved nature of the inner element in this circumstance causes the exposed end of the inner element to be substantially out of the plane P containing the distal end portion of the outer tube. A whole family of these "out of plane" curves can be achieved as desired by the user by curving the outer tube more or less and exposing more or less of the inner catheter or element as illustrated above in Fig. 15B. Figs. 15-15B illustrate an important and unexpected feature of the present invention—rotational change in the relationship of an inner element with a distal curved portion and an outer tube with a distal curved portion change the shape of possible catheter configurations obtainable so that out-of-plane shapes are achieved.

There is nothing in this art to suggest that the distal end portion of outer catheter 57a in Ganz et al. is not planar with both inner catheter 11a (in Fig. 12) and inner catheter 11b (in Fig. 13). Note that the distal end portion of Ganz et al. distal of bend 67a in Fig. 12 does not point in the same direction as that same portion in Fig. 13. It is respectfully submitted that this change in position is certainly sufficient to allow the corresponding

inner catheters (11a and 11b) to both be coplanar with the distal end portion of outer catheter 57a in their respective positions. The Examiner's position could have merit if the drawings of the distal end portions of outer catheter 57a were the same in Figs. 12 and 13. But they are not. Claim 10 is allowable for all these reasons.

Claims 11-16 depend from claim 10 and are allowable therewith. Claim 11 further specifies that the inner medical element is fixed rotationally with respect to the catheter tube. As discussed above, Ganz et al. lacks this feature, there is no motivation to combine the references as suggested by the Examiner to add it, and even if the combination were made it would not work. Claim 13 specifies that at least one of the catheter tube and the inner medical element are remotely controllable to form curves in their distal end portions. As discussed above, there is no remote control (pullwire) in these references. The Examiner adds the Badger reference to provide this feature, but there is no motivation in this art to complicate the structure of Ganz by adding a third reference. Claim 13 is allowable for this reason as well.

Claim 14 requires that the first and second curves are separated in operation by no more than three times the smaller of the first and second radii of curvature. The smaller radius of curvature in Ganz et al. is that of bend 105 and bend 105b. The curve in outer catheter 57a appears to be separated from the curve at bend 105 (and that at bend 105b) by roughly ten times the relevant radius of curvature. Claim 15 provides that the first plane is fixed at an angle of approximately ninety degrees with respect to the second plane. There is no indication of any out-of-plane shape in Ganz et al., much less one of 90 degrees. Claim 16 requires that the first and second curves in operation are separated by no more than three times the smaller of the first and second arc lengths of those

curves. Like claim 14, the arc length of bends 105 and 105b are the relevant arc lengths, and the curve in outer catheter 57a is substantially farther than three arc lengths away from the curve of bends 105 and 105b. These claims are allowable for these reasons as well.

Claim 24 depends from claim 19 and provides for proximally fixing the distal end of the combination catheter substantially out of the first plane. Ganz et al. does not have this feature (and, as explained above, neither do the other references). Moreover, there is no reason to add such a feature to Ganz et al.—also as discussed above. Claim 26 similarly requires proximally fixing the inner medical element against translation and rotation with respect to the catheter tube. This feature is not shown or suggested in this art.

Claim 28 is an independent claim that includes the step of "forming the combination catheter into a shape in which the distal end of the combination catheter is disposed substantially out of the first plane for a period of time sufficient to permit medical use of at least one of the catheter tube or the inner medical element", and the step of "proximally fixing the inner medical element against translation and rotation with respect to the catheter tube." As discussed above, Ganz et al. lacks the out-of-plane feature and lacks any fixing feature. There is no motivation in the art to combine the references as suggested by the Examiner, and in fact the structure in Ganz et al. teaches away from such a combination. And the secondary references do not show these features anyway. Claim 28 is allowable for all these reasons.

Claim 31 depends from claim 10 and is allowable therewith. It also provides that the second curve is disposed substantially out of the first plane by **rotating** the inner

medical element with respect to the catheter tube. Ganz is designed to function in a way that the rotation required by claim 31 cannot occur. Since this feature is directly the opposite of what is taught by Ganz, claim 31 is allowable for this reason as well.

Claim 32 depends from claim 19 and is allowable for the same reasons as that claim. It further requires that the forming step includes rotating the inner medical element with respect to the catheter tube. As discussed above, Ganz et al. is designed to insure that such rotation does not occur and that the inner catheter emerge with a single, predetermined orientation. Claim 32 is allowable for all these reasons.

Claim 33 depends from claim 10 and is allowable therewith. It further specifies that the step of fixing includes proximally fixing the distal end of the combination catheter substantially out of the first plane. Such a proximal fixing is absent from this art (as explained above), so claim 33 is allowable for this reason as well.

Claim 34 also depends from claim 10 and is allowable for the same reasons as that claim. Claim 34 further requires that the step of fixing includes proximally fixing the inner medical element against translation and rotation with respect to the catheter tube. As discussed above, proximal fixing is not shown or suggested by this art. Claim 34 is allowable for all these reasons.

Rejection of Claims 19-22 under 35 U.S.C. §§ 102(b) or 103(a) over Sylvanowicz alone or in view of Voda.

The Examiner has taken the position that the present invention is anticipated by or obvious in view of Sylvanowicz. This position is inconsistent with the reference, as the following discussion will illustrate.

The Examiner has two assertions in connection with Sylvanowicz, both of which are incorrect. One is that in moving the Sylvanowicz catheter from the figure 12 position

to the figure 14 position it must inherently pass through the claimed out of plane configuration. The other is that if one of the figure 12 or the figure 14 positions are in plane, the other must be out of plane, as set forth in the present claims. Neither assertion is true.

Figures 12 and 14 of Sylvanowicz are set forth below.

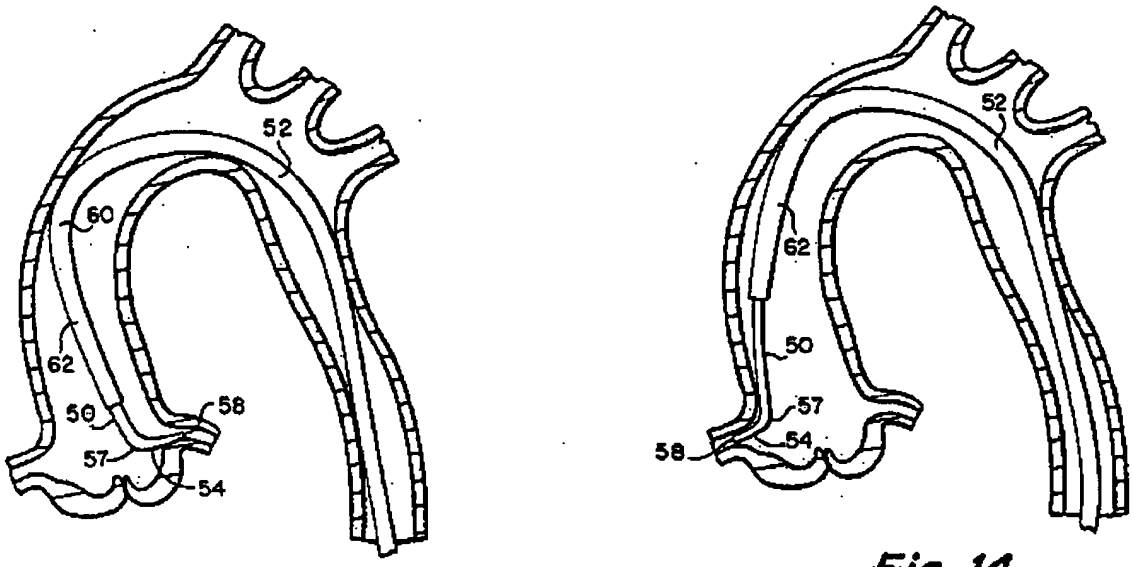


Fig. 14

The Examiner's approach ignores a fundamental limitation of the claim. Claim 19 (and the other claims at issue) clearly requires that the "distal end portion" of the catheter tube be fixed (i.e., assume and maintain) in a curved configuration. Note the reference is not to the "distal portion", but to the "distal end portion". The Examiner's interpretation of the Sylvanowicz reference might have some merit if the limitation were the "distal portion", since everything distal of the proximal end is a distal portion, but it is clearly erroneous since the limitation is the "distal **end** portion". "End" has a well-recognized meaning, which the Examiner has routinely ignored. The Examiner refers not to the

distal end portion of Sylvanowicz, but rather to some intermediate portion that suits his purposes.

As the above drawings from Sylvanowicz clearly show, the distal end portion 62 of catheter tube 52 in Sylvanowicz is straight in Fig. 12 and in Fig. 14, and there is no indication that the distal end portion 62 is curved at any time in moving from the Fig. 12 position to the Fig. 14 position. In fact, Sylvanowicz specifically identifies portion 62 as "The outer tube has a relatively large radius curve 60 formed adjacent its distal end and a **straight distal segment** 62 extending from the curved portion 60." (col. 6, ll. 53-56)(Emphasis added). Thus, the distal segment of Sylvanowicz **that includes the end**, i.e., the distal end portion, is straight, not curved. Since the distal end portion of the catheter tube in Sylvanowicz is straight, it is incapable of providing the surprising interaction of two curves which results in the inner element being thrown out of plane with respect to the outer catheter tube. **This difference alone is sufficient to distinguish Sylvanowicz—Sylvanowicz is operating in a completely different manner and does not achieve the claimed result of the present invention.**

The Examiner takes the position that in moving from the Fig. 12 to the Fig. 14 position, the catheter must go out-of-plane. In this connection he states: "Since the inner catheter is taught to be rotated in going from the left coronary artery to the right, the distal end of the inner catheter will be formed in an out of the plane defined by the outer sheath for a sufficient time to perform medical use of the inner catheter, **namely a recatheterization of the coronary arteries by rotation.**" But that conclusion is false. To start with there is no indication in the art that rotation to form a new shape is a "medical use". Claim 19 specifically require such a medical use. It is improper for the Examiner to

make up "medical uses" to fit his requirements. This assertion by the Examiner brings to mind the quote from Alice in Wonderland where Humpty Dumpty says, "A word means what I want it to mean, nothing more, nothing less." This, of course, was very frustrating to Alice, and it remains so today.

In addition, this position of the Examiner is inconsistent with the language of the claims, including the language of claim 19. Claim 19 requires "forming the combination catheter **into a shape** . . . for a period of time sufficient to permit medical use". The "medical use" invented by the Examiner does not involve "a shape" as required by claim 19, but an infinite number of shapes as the inner catheter is rotated. Claim 19 is, for all these reasons, patentable under §§ 102 and 103 over Sylvanowicz, since Voda does not eliminate the deficiencies present in the Sylvanowicz reference.

Claims 20-22 relate back to claim 19 and are allowable therewith.

Rejection of Claims 10-16, 22, 24, 26, 28, 29, 31-34 under § 103(a) over Sylvanowicz alone or in view of Voda, Saice or Quinn

Initially, it should be pointed out that if the rejection really requires four different references, then it is highly unlikely that the invention is either anticipated or obvious. Moreover, the rejection of these claims suffers from the same defects as the rejection of claim 19, discussed above. For example, claim 10 requires fixing the "distal end portion . . . **in a second curve** . . . **disposed substantially out of the first plane** for a period of time sufficient to permit medical use". As will become apparent below, Sylvanowicz completely lacks the out of plane feature of the "distal end portion" in either the Figure 12 or the Figure 14 configuration. (And, during movement from one to the other, there is not "a second curve", but rather an infinite number of curves.) The Examiner's position is also inconsistent with the actual language of Sylvanowicz, as explained below.

The present claims clearly define the plane with respect to the **curved distal end portion** of the outer catheter, not with respect to the outer catheter as a whole. It is only by ignoring the plain language of the claim and of Sylvanowicz ("**straight** distal segment 62") that the Examiner is able to reach his erroneous conclusion as to what must happen.

Similarly, the Examiner recognizes that the configuration of Fig. 12 in Sylvanowicz is planar, but appears to take the position that the other configuration (that of Fig. 14) must be out-of-plane. The Examiner is incorrect, as can be easily demonstrated. In col. 7, lines 25-30, and 46-52 of Sylvanowicz, formation of the configuration for entering the right coronary artery ostium (the configuration of Fig. 14 is described, as follows:

> "Such withdrawal shifts the location of the primary curve proximally along the length of the catheter which cause a repositioning of the **distal portion of the inner catheter** so that it **points toward the right coronary ostium**."
>
> "By withdrawing the outer tube proximally to reposition the primary curve, **the distal segment 62 [of the outer tube]** is reoriented and **points toward the right coronary ostium**. Thus, when extended, the position of the protruding distal portion of the inner catheter shifts from the position as shown in FIG. 12 toward a position toward the right coronary ostium." (Emphasis added)

Note that the inner catheter in Sylvanowicz is disposed in the outer tube and exits from the distal tip of distal end segment 62 (see Fig. 14, for example). These elements are, therefore, co-linear at the point where the inner catheter exits the outer tube. If the distal portion of the inner catheter points toward the right coronary ostium, and the straight distal segment 62 points toward the rights coronary ostium, then those two elements **must**

be in the same plane. If they were not co-planar when in the Fig. 14 configuration, it would be physically impossible for both the distal segment 62 of the outer tube and the distal portion of the inner catheter to both point toward the right coronary ostium.

This difference between Sylvanowicz and the presently claimed invention is seen more clearly by examining the following figures from the present application.

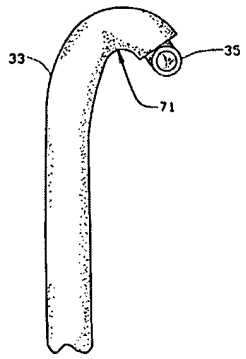


FIG. 15

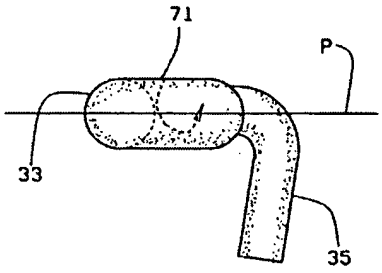


FIG. 15A

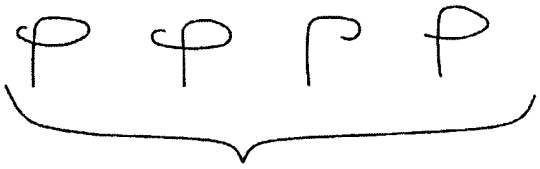


FIG. 15B

In Fig. 15 of the present application, the distal end portion of the catheter tube is clearly curved in the plane of the paper and the inner curved element, as a result, has its distal end portion thrown out of the plane of the paper (as shown in Fig. 15A). The two curves (that of the curved distal end portion of the catheter tube and that of the curved distal end portion of the inner element) are in two different planes, which provides an overall out-of-plane shape as illustrated in Fig. 15B.

Contrast this with Sylvanowicz in which a single plane always contains the straight distal end portion 62 of the catheter tube and curved distal end portion 54 of the inner element, **even as the inner element is rotated from one position to the next.** The result is different in Sylvanowicz because the distal end portion 62 of the catheter tube is straight, not curved as required by the present claim. An infinite number of planes pass

through the straight distal end portion 62 of the catheter tube in Sylvanowicz, and so in the Fig. 12 and Fig. 14 positions in Sylvanowicz and in all positions in between, the distal end portion 54 of the inner element lies in one of those planes.

Moreover, no one has recognized the huge advantages of being able to obtain this entire family of "out of plane" shapes from two curvable elements. In fact, such a construction is immensely useful. It permits two planar elements (the inner element and the outer tube) to interact to provide an out-of-plane position for the distal end. It should be recognized that out-of-plane positioning is extremely useful in the human body. Yet Sylvanowicz fails to even hint at this feature. The claimed feature is simply not inherent in Sylvanowicz.

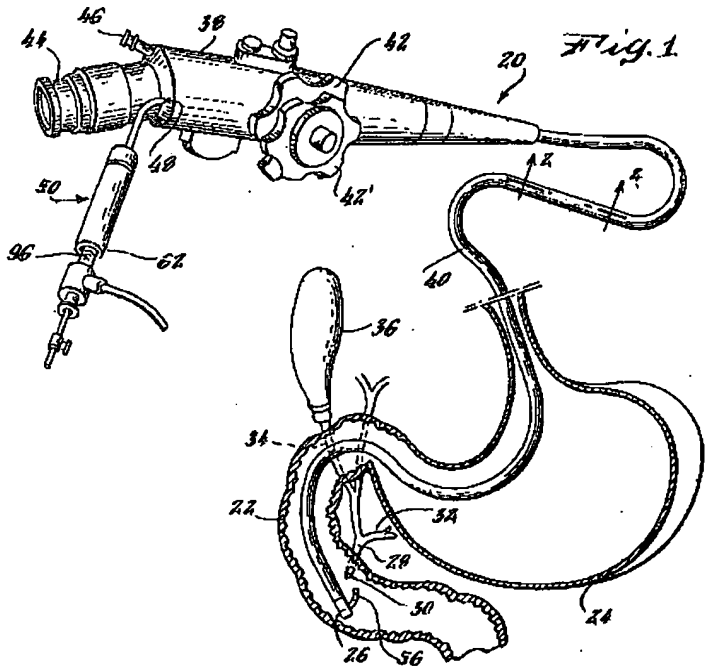
The Examiner cites numerous references for fixing, but none of them remedy the fundamental defect in Sylvanowicz as a reference—the lack of formation of the distal end portion into an out of plane shape. Claim 10 is allowable for all these reasons.

Claims 11-16 depend from claim 10 and are allowable therewith.

Rejection of claims 10-16, 19-22, 24, 26, 28, 29, and 31-34 under 35 U.S.C. 103(a) over Petruzzi (U.S. Pat. 4,474,174) in view of D'Amelio et al. (U.S. Pat. No. 4,659,195) and Ueda (U.S. Pat. No. 4,617,914)

The rejection based upon Petruzzi involves a fundamental misconception on the part of the Examiner as to how Petruzzi works. The affidavit of Dr. Giuseppe Aliperti filed herewith reveals that the Examiner's construction of Petruzzi is incorrect and totally inconsistent with actual devices, whereas the applicant's construction of Petruzzi is totally consistent with real world devices. This is not, of course, surprising, since the Examiner's construction of Petruzzi would result in a device that would be impractical to use—all as explained below.

Petruzzi can best be understood from an examination of its drawings. Fig. 1 is set forth below:



As can clearly be seen in this drawing, Petruzzi has a straight distal portion of the outer tube whose longitudinal axis is in the same plane as the distal portion of a curved inner element 56. As shown in Fig. 3, below, the inner element can be extended out through an opening in the side of endoscope 40 and its curve may be changed by means of a movable wedge 92.

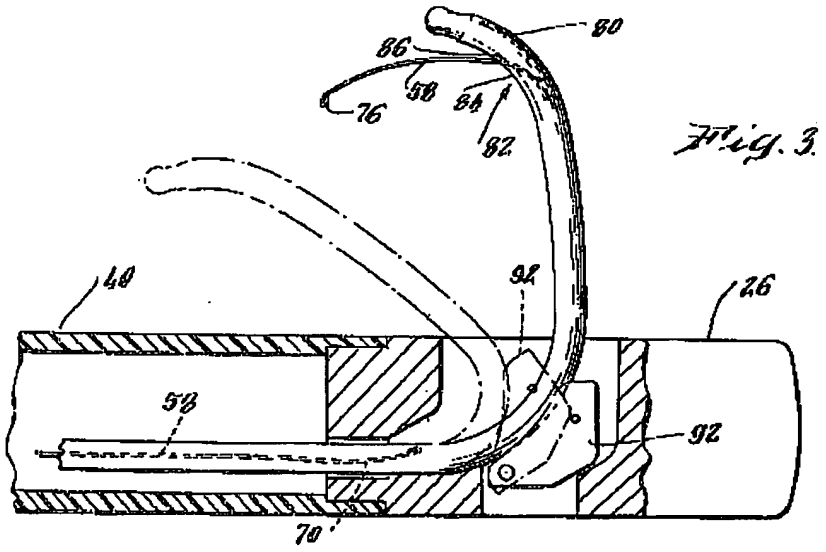


Fig. 3.

Curved element 56 and a tool 58 contained therein are shown in more detail in Fig. 3 from Petruzzi, set forth above (curved element 56 being unlabeled in Fig. 3, but being identified in Fig. 1). Note that there is no indication the inner element 56 in Petruzzi will occupy any plane other than the one defined by the longitudinal axis of the outer tube. In fact, in Fig. 1 of Petruzzi the window or opening in the endoscope (shown but not labeled in Fig. 3 above) through which member 56 extends cannot be seen, thereby indicating that the plane defined by the distal end portion of outer element is not in the plane of the paper, but rather is in some other plane—presumably the one including element 56 and a valve 30 known as the ampulla of Vater.

The Examiner in this Office action again takes the position that Petruzzi must show the claimed out-of-plane configuration of the present invention, stating:

"It is apparent to those of ordinary skill in the art that such an out of plane configuration **would be necessary** in order to access the the [sic] ampulla of Vater."

As shown in the affidavit of Dr. Aliperti filed herewith, it is not "necessary" that the claimed "out of plane configuration" be used to access the ampulla of Vater. In fact, the Examiner's conclusion to the contrary apparent is based upon either a misreading of Petruzzi or of one of the secondary references, since Petruzzi, as set forth below, cannot work in the manner postulated by the Examiner. Perhaps the Examiner's error in this regard continues to flow from his refusal to recognize that the claims of the present application specifically require that the "distal end portion" be formed into the out of plane shape. It is not enough that any "distal portion" form such a shape.

The drawings of Petruzzi, namely Fig. 1, which hide the opening in the endoscope that faces the ampulla of Vater are inconsistent with the Examiner's speculation but are totally consistent with a manipulation which result in the distal end, the window, and the guiding catheter of Petruzzi being "in plane", not out-of-plane as required by these claims.

Moreover, the claimed out-of-plane shape of the distal end in Petruzzi, as explained below, is unachievable since the distal end is straight, solid, and unbendable. This is shown in Fig. 3 of Petruzzi. That Figure is set forth below.

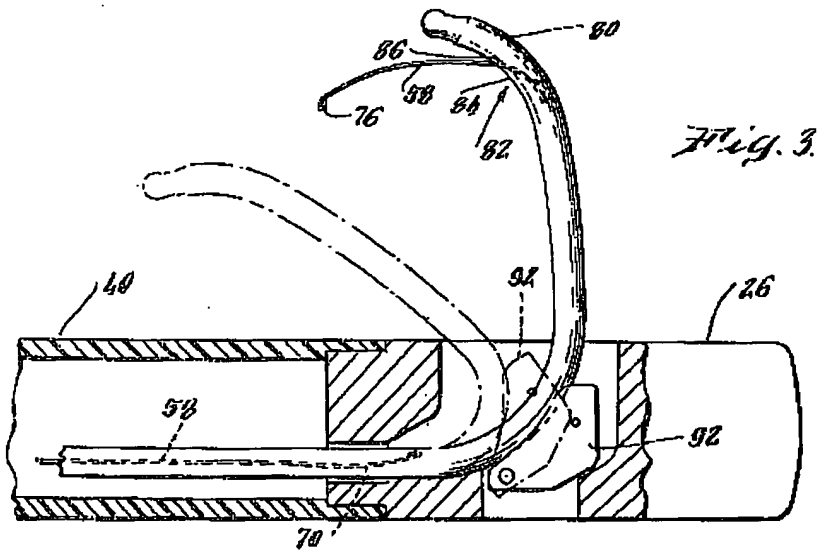


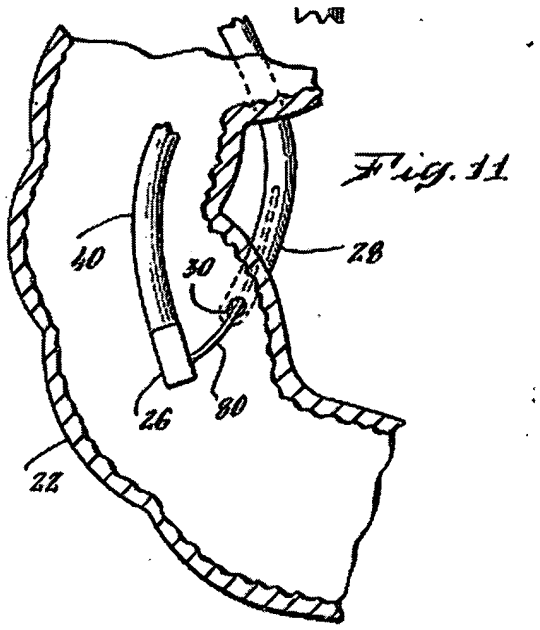
Fig. 3.

Note that there is absolutely no mechanism in Petruzzi to cause the distal end portion to bend in any way. It is solid. The inner catheter that comes out of the side of this straight, solid portion is bendable by the wedge 92, but there is no similar mechanism for forming a curve in the distal end portion of the outer tube. Note as well that the movement of element 82 in Petruzzi is in the plane of the window of the outer catheter. It appears that the structure of Petruzzi, as would be expected, in fact mechanically confines element 82 to stay in plane. Moreover, there is absolutely no structure provided to move element 82 out of that plane.

With the apparatus of Petruzzi, the only way to direct the catheter to the ampulla of Vater is by pointing the window of the endoscope straight toward the ampulla. This is a matter of basic physics. If the window of the endoscope were positioned in a left/right manner as theorized by the Examiner, the medial wall (and not the posterior wall containing the ampulla) would be visualized. In that case, since the ampulla would not be in sight, it could not be catheterized. If the window were not pointing at the ampulla,

the user would not have any idea where to direct the catheter. And if the catheter were disposed out-of-plane with respect to the window/ampulla plane, it would not (could not) go into the ampulla.

Importantly, one should note that one does not see the window in Fig. 1 or Fig. 11 of Petruzzi, which is totally consistent with the window and the optics facing the ampulla in the posterior wall—allowing the catheter to be extended *in the plane* of the window and ampulla so that all elements are clearly in a single plane. For convenience, Fig. 11 of Petruzzi is shown below:



With the Petruzzi device, unless the object (in this case the ampulla of Vater) is in line of sight view, it cannot be catheterized. The Examiner's theory of events—looking in one direction and catheterizing in another which you cannot see and do not know the location of—is impossible with the Petruzzi device. Petruzzi *could* show many things, but it does not show or suggest this invention.

Claim 10, as discussed above in connection with Sylvanowicz, is a method claim that requires fixing the distal end portion of the inner medical element in a second curve such that the distal end of the inner medical element is disposed substantially out of the first plane for a period of time sufficient to permit medical use of at least one of the catheter tube or the inner medical element. As explained above, Petruzzi does not and cannot disclose this feature. In fact, endoscopes like those disclosed in Petruzzi are not designed for "fixing the distal portion of the inner medical element". Rather, endoscopes provide a stable platform from which an inner element is extended or moved to a desired position. "Fixing" the inner element with respect to the endoscope runs counter to the ordinary and normal operation of an endoscope. An inner element that is fixed with respect to the endoscope to form a shape (the present invention) cannot be extended or moved with respect to the endoscope (as is desired in conventional endoscope operation). Conventional endoscopes and the presently claimed invention are mutually exclusive.

Claim 10 also requires medically using at least one of the catheter tube or the inner medical element while the distal end of the inner medical element is disposed substantially out of the first plane. This is also absent from Petruzzi, since Petruzzi completely lacks the out-of-plane feature.

Apparently recognizing the weakness of this rejection, the Examiner tries to combine Petruzzi with **multiple** other references. As an initial matter, it should be noted that there is no motivation to combine Petruzzi with a single other reference, much less multiple references. Nothing in Petruzzi or the art indicates that Petruzzi fails to achieve its purpose or could be improved. Yet the Examiner, using hindsight provided by the present invention, hypothecates a combination of Petruzzi with these other references.

That combination, even ignoring the absolute lack of any motivation to make it, must fail. The D'Amelio et al reference (U.S. Patent 4,659,195) unequivocally states that the two elements should not go out of plane, stating:

> "objective assembly 46 **must articulate in the same plane** as the guide member 36." Col. 8, lines 37-39.

If the combination of Petruzzi and D'Amelio et al were to be made (despite the total lack of motivation), it would not result in an out-of-plane shape because D'Amelio et al teaches that it is imperative ("must") that the two tubes be "in the same plane". This reinforces applicant's argument above concerning the teaching of Petruzzi of planar operation.

The fact that D'Amelio et al teaches that out of plane shapes "must" be avoided makes any rejection of these claims based upon that reference legally and logically unsound. It also reinforces applicant's position concerning all these references, since the reason D'Amelio et al teaches avoiding out of plane shapes is most probably applicable to the other references, including Petruzzi.

Nor is the Examiner's rejection helped by U.S. Patent 4,617,914 to Ueda. Ueda discloses an "End Curving Device for Endoscope", but where is the motivation to provide such a structure for Petruzzi? The structure of Petruzzi is already complicated and crowded internally. Why would anyone want to make it more complicated when it apparently achieves its desired purpose? The only reason to make the combination suggested by the Examiner is the hindsight provided by the present invention. This is improper.

Claim 10 is allowable for all these reasons.

Claims 11-16 depend from claim 10 and are allowable therewith and for the reasons set forth in the previously filed appeal brief.

Claim 19 is an independent method claim that also requires the defined out-of-plane feature. It is, therefore, allowable for the same reasons as claim 10. Claims 20, 21, 22, 24, and 26 depend from or relate back to claim 19 and are allowable therewith.

Claim 28 is another independent method claim that includes the out-of-plane feature of claims 10 and 19, as well as the proximal translational and rotational fixing feature of claim 26 (discussed in the appeal brief, all the arguments of which are incorporated by reference into the present response). Claim 28 is, therefore, allowable for all the same reasons as those claims.

Claim 29 is an independent method claim directed to forming the combination catheter into first and second out-of-plane shapes and proximally fixing those shapes for periods of time sufficient to permit medical use. None of the references teaches the proximal fixing for even a single out-of-plane shape, much less two. More significantly, the prior art is mute concerning forming first and second out-of-plane shapes. Claim 29 is unquestionably allowable.

Claim 31 depends from claim 10 and is allowable along with that claim. It further provides that the second curve is disposed substantially out of the first plane by rotating the inner medical element with respect to the catheter tube. None of the references disclose the out-of-plane feature, much less the relative rotation that causes it. Claim 31 is allowable for this reason as well.

Claim 32 depends from claim 19 and also is directed to the feature of forming the shape by rotating the inner medical element with respect to the catheter tube. The art, as

discussed above in connection with claim 31, lacks this feature, so claim 32 is allowable for this reason as well.

Claims 33 and 34 depend from claim 10 and are allowable for the same reasons as that claim.

Rejection of Claims 10-16, 19-22, 24, 26, 28-29 and 31-34 under 35 U.S.C. § 103(a) over D'Amelio et al in view of Ueda, further in view of Forester or Patel

Any rejection of these claims based upon D'Amelio cannot stand. All the claims of the present application are directed to the "out of plane" feature, discussed in detail above. But D'Amelio et al reference (U.S. Patent 4,659,195) unequivocally states that the two elements should not go out of plane, stating:

> "objective assembly 46 **must articulate in the same plane** as the guide member 36." Col. 8, lines 37-39.

The word "must" in this quote renders this rejection baseless. No combination of any reference with D'Amelio et al can, consistent with D'Amelio, have an out of plane shape. This rejection should be summarily withdrawn. (The rejection is further suspect by the multiple number of references the Examiner considers necessary to find all the elements of these claims. The art is simply not directed to the present invention, so the Examiner appears to be grasping at straws—in this case grasping at references—to build a case for unpatentability that is not present in the references.)

If the Examiner decides to persist in such an untenable rejection, the following should be considered. D'Amelio et al. is fundamentally different from the presently claimed invention. D'Amelio et al. requires four (4) operating cables (pull-wires) 64 to manipulate the flexible end member 60 of a borescope 34 for inspecting a jet engine. The reason for four cables is stated in the following passage from D'Amelio et al.:

"With the cables 64 placed at spaced circumferential locations around the inner surface 66, the distal collar 58 can be moved in as many directions as there are cables. Since there are four cables at equally spaced circumferential locations in the illustrated embodiment, that construction provides movement in four different directions lying in two different intersecting planes."

If D'Amelio et al. were actually shaping and forming as required by the claims of the present application, only one of the pull-wires would be needed (as in the present application). The other three would be superfluous. Similarly, if D'Amelio et al. were shaping and forming as required by the present claims, two pull-wires would be more than sufficient. Yet D'Amelio et al. uses four. D'Amelio et al. is clearly directed to a very different device being used for a very different purpose.

As an aid to understanding the D'Amelio et al. reference, the following chart is provided which sets forth relevant passages from D'Amelio et al. and their relevance to the features of the present claims, with emphasis added:

Passage from D'Amelio et al.	**Relevance to Present Application**
"A problem arises in using presently available flexible devices for the internal inspection of complex articles of manufacture such as interior regions within jet engines. For example, certain compartments within the engine, such as the aforementioned regions	This passage teaches that the D'Amelio et al. device, unlike most medical catheters, is designed to function in an environment "characterized by relatively open spaces and few appropriate supporting surface[s] readily available to guide the objective end of the

within the burner cans and the turbine, are at present effectively inaccessible to viewing by an inspector. Such inaccessibility is the case even with the use of an inspection device such as an endoscope because the articulation of the inspection device requires some sort of guiding surface, such as the interior wall of the colon, to orient and support the inspection device. In contrast to the colon of the human body, a jet engine has **an interior characterized by relatively open spaces and few appropriate supporting surface readily available to guide the objective end of the inspection device.** In addition, presently known endoscope designs, even when used for their originally intended purpose, are not easily able to negotiate all colon configurations without **substantial risk of puncturing the colon wall.**" Col. 2, lines 3-22.	inspection device." This is in contrast to the present invention. Various out-of-plane shapes interact with the walls of various human vessels. The present invention permits the formation of these shapes in situ, while the D'Amelio et al. reference teaches avoiding the walls. Note that even in the case of colonoscopy, the D'Amelio et al. reference teaches the desirability of avoiding the colon wall. See, col. 2, lines 19-22.
"Additional **problems** with the **known devices** are that the guide tube can **only articulate in two directions**, i.e. in one plane, which makes it very awkward and time consuming to get the	Teaches the desirability of being in the "center of the burner can" for inspection. Shows that the patent is directed toward positioning the distal end ("get the distal end thereof in the

distal end thereof in the **proper location** for feeding the viewing scope through the crossover tubes. This is generally done by lining up in the plane by which articulation of the distal end thereof is possible and then jumping or jogging the cable around to exactly line it up **so that the viewing scope can be located correctly**. Finally, the known scopes cannot easily accomplish inspections of the louvered section of the burner can or the first stage stationary vanes and first rotor as they **cannot be easily located in the center of the burner can** for ease of such inspection." Col. 3, lines 4-17.	proper location") rather than forming a particular shape, such as the claimed out-of-plane shapes.
"The distal end is slidably inserted through a tubular elongated flexible guide member which has an operating head at a near end and a distal collar at a remote end capable of **deflecting in four discrete directions**. The objective assembly of the borescope is capable of deflecting in two discrete directions." Col. 3, lines 31-37.	Talks about deflecting in four discrete directions and two discrete directions. No hint that out-of-plane as defined in the claims is desirable or even possible with such a construction. D'Amelio et al. invention is thus directed to maximum flexibility in the placement of the distal end, not its shape.
"The device of the invention provides for a	Talks about deflection in two different planes

four-way (two-plane) articulation of the flexible guide tube whereas known devices provide for only a two-way (one-plane) articulation of the guide tube. As with the prior art, the present invention also provides for a two-way (one-plane) articulation of the viewing scope or borescope." Col. 3, lines 60-66	with the D'Amelio et al. device, but again totally fails to realize that one can achieve distal configurations that are out of either of those two planes.
"Since there are four cables at equally spaced circumferential locations in the illustrated embodiment, that construction provides **movement in four different directions** lying in two different intersecting planes." Col. 6, lines 27-31.	Teaches movement in four different directions lying in two different intersecting planes, but again fails to even hint that the distal end can be disposed out of either of those two intersecting planes. D'Amelio contemplates planar movement in either of two selected planes, but not an out-of-plane shape as defined by the claims.
"**Extension and retraction** of the telescoping support member 38, as shown in FIGS. 9A and 9B is effected by rotating knurled nuts 38A AND 38B to grasp and release the internal tubular members in the conventional fashion." Col. 6, lines 35-39	Knurled knobs 38A and 38B are taught as holding against longitudinal movement only. (Free to turn at another segment, which allows rotation.)
"However, it will be appreciated that even in	Describes the longitudinally retracted and

the retracted position of the flexible body 42, the objective assembly 46 can still be manipulated to the dotted line positions indicated in FIG. 3A. In its **retracted position**, the objective assembly 46 may typically extend approximately 1.4 to 2.0 inches beyond the distal collar 58 and in the **extended position**, approximately 6 to 8 inches or longer beyond the distal collar 58." Col. 6, lines 57-65	extended positions of the D'Amelio et al. device. Again, no reference to fixing the two parts of the device against rotation.
"The retention spring 68 is preferably fashioned from flat stock so as to occupy minimal space when viewing the tubular member 60 from an end. The retention spring thus serves to retain the operating cables 64 and their surrounding outer tubes in their proper respective positions even though **the borescope 34 is twisted relative to the tubular member 60**. Specifically, the retention spring 68 prevents the operating cables 64 from spiraling with the borescope 34 **as the latter is spun inside the tubular member 60**. In the absence of the retention spring 68, the operating cables	Far from desiring fixing of the borescope of D'Amelio et al. against rotational movement, such rotational movement is desired to accomplish its purpose.

64 would tend to **spin** with the borescope 34 which would not only cause interference between the borescope and the tubular member 60, but also would cause unreasonable and unnecessary wear on the parts." Col. 7, lines 13-25.	
"These differences include the capability of the guide member 36 having four-way, that is, two-plane articulation." Col. 7, lines 30-32.	"Reference to "two-plane articulation" but no clue that out-of-plane shaping is possible.
"In a typical maneuver, as illustrated in FIG. 13, while the objective assembly 46 is viewing the liner of the burner can 74 opposite the igniter port 76, the distal collar 58 is articulated by means of the actuating knobs 62 and 63 to enable the objective assembly 46 to locate a crossover tube 78 between the adjacent burner cans 74. With continued manipulation by the operator of the inspection system 30, the distal collar 58 is moved closer to the crossover tube 78 as illustrated in FIG. 14 **while keeping the tube 78 in the center of view** of the objective assembly 46."	"Illustrates how the D'Amelio et al. device relies solely on optical feedback to place the device properly. Also illustrates that the location, not the shape, of the distal end is the only thing of interest to D'Amelio et al.
"During this entire procedure, areas of interest	Again describes operation of the D'Amelio et

within the burner cans can be inspected by articulating the objective assembly 46 and the distal collar 58, feeding the system 30 to an extreme end of a burner can, then extending the objective assembly 46. The inspection itself is performed as the system 30 is withdrawn from each burner can. To inspect an area around a crossover tube through which the objective assembly 46 and distal collar 58 are inserted is generally illustrated in FIG. 19. For this view, the objective assembly 46 **must articulate in the same plane** as the guide member 36." Col. 8, lines 28-39	al. device, and in particular teaches (with respect to Fig. 19) that the inner and outer elements "must articulate in the same plane." This is a clear teaching away from the present invention.
"There are numerous advantages inherent in the present invention over the known devices. In the first place, the four-way articulation of the steerable flexible guide member 36 allows a quicker, more **precise positioning** of its distal end before the objective assembly 46 is extended. This is important because of the **different positional locations** between the igniter port 76 and the crossover tubes 78 and other elements to be inspected by the device."	D'Amelio et al. is teaching positioning of the distal end—not shaping. D'Amelio et al. is indifferent to the shape of the device. Position is all that matters in the D'Amelio et al. patent.

Col. 8, lines 40-48.	
"This is done by placing the distal end of a flexible guide member 36 **in the center of the burner can** 74 as illustrated by dotted lines in FIG. 1. The invention, by virtue of its four-way articulation, permits the distal collar 58 to be easily **placed in the center of the burner can** and then to **spin or rotate** the objective assembly 46, which is positioned near the louvered area 80, in a 360 degree arc so as to inspect each one of the louvers. This easily performed operation contrasts with the prior art constructions which are restricted by a two-way articulation at the end of their equivalent of the tubular member 60. Such prior art devices cannot be **positioned** very easily in the center of a burner can but must be **located in several positions** in order to inspect all of the louvers around the outside of the burner can." Col. 8, line 55 to col. 9, line 2.	Teaches placing the end of the outer element in the center of the burner can (again placement only). Also teaches free rotation of the inner element with respect to the outer element (not rotational fixing). Articulation of the outer member in four directions (apparently never at the same time) is used solely to facilitate the placement of the end of the device in the center of the burner can. At that point, the inner member is spun or rotated to observe all the louvers. This should be contrasted with applicant's out-of-plane feature, which would not provide this functionality. A catheter with an out-of-plane distal tip could not, by rotation of the inner element with respect to the outer, result in observation of the various louvers. This difference is fundamental. D'Amelio et al. is interested in positioning—the present invention is directed to shaping.
"It is also noteworthy that the first stage of the jet engine 32 can be much more easily viewed by the invention. This is depicted in FIG. 21	Teaches positioning in the center of the burner can for yet another inspection operation.

which illustrates the distal collar 58 being **precisely located within the burner can** next to the fixed guide vanes 82 of the first stage of the jet engine 32. In this manner, the objective assembly 46 can be fed through the vanes in a precise manner and displaced accurately adjacent the first stage rotor 84. The rotor can then be turned by hand for complete inspection by the system 30. While the prior art can theoretically accomplish this end result, the fact is that in order to inspect the rotor 84 and the fixed guide vanes 82, the objective assembly 46 must repositioned several times because of the awkwardness in positioning it in the first place. This awkwardness results from the limited two way articulation system previously employed. Thus, the known inspection systems must work around the area to be inspected with several positions for the end of the guide tube. In contrast, the invention merely requires that the distal collar 58 be set **near the center of the burner can** so that when the objective assembly 46 of the

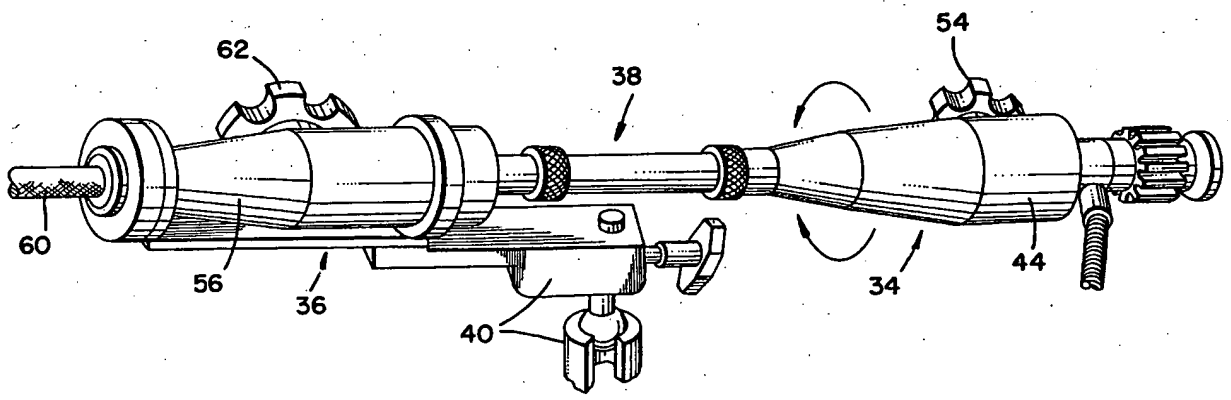
borescope 34 is fully extended, it will be in the precise position to get into the rotor area." Col. 9, lines 3-26.	
"Also, it should be noted that when the control head 44 is moved relative to the operating head 56 and **spun or rotated** in a concentric manner with the tubular member 60, the proximal end thereof is relatively linear and rigid. Another element of the construction of the present invention which adds considerably to the reliability of the invention is the provision of the retention spring 68 which eliminates potential problems of the operating cables 64 twisting with the flexible body 42 as the latter is **spun or rotated** inside the tubular member 60." Col. 9, lines 46-57.	Again teaches free rotation of the inner element with respect to the outer element—not rotational fixing.

Preliminarily, it should be noted that there is nothing in D'Amelio et al. which would motivate one of ordinary skill in the art to make any modifications to the D'Amelio et al. apparatus whatsoever. The apparatus appears to adequately solve the problems at hand, and there are no hints of any deficiencies in D'Amelio et al. Moreover, the Examiner has not pointed to anything in other prior art which would suggest making any modifications to D'Amelio et al.

The Examiner does cite the US patent classification system and Ueda for braking systems to maintain articulated curves. Although that may be true in the abstract, it is hardly true in the context of the present rejection which includes D'Amelio et al. (Of course, as pointed out above, the Examiner misreads D'Amelio et al. to include preventing rotation.) D'Amelio et al., when correctly read, teaches free rotation because that is how it works—a can is entered and the device is spun through 360 degrees to inspect the can. Adding a device to fix D'Amelio et al. against rotation is like adding a device to a paving machine to put potholes in a road—no one trying to achieve the desired result would do it. The Examiner's use of the US classification system could be appropriate in some other rejection, but not in a rejection that includes D'Amelio et al.

Turning to the D'Amelio et al. disclosure itself, in addition to Figs. 13-16 and 19, Fig. 3 is set out for convenience below. Fig. 3 gives an overview of the two major components of the D'Amelio et al. device.

FIG. 3.



As can be seen from Fig. 3, the D'Amelio et al. device includes an inner portion (borescope 34) which is designed to be rotatable (as indicated by the arrows) with respect to an outer guide member 36. Figs. 13-16 and 19, on the other hand, illustrate various ways in which the D'Amelio et al. device is used.

FIG. 13.

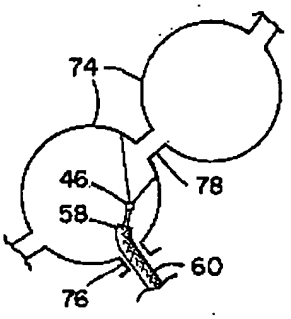


FIG. 14.

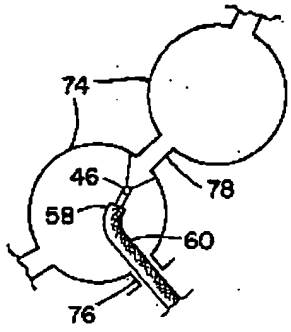


FIG. 15.

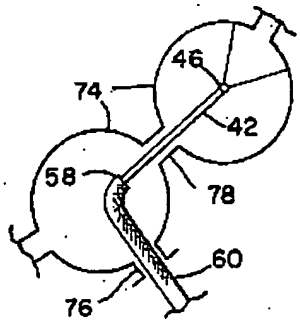


FIG. 16.

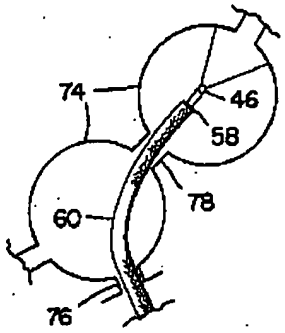
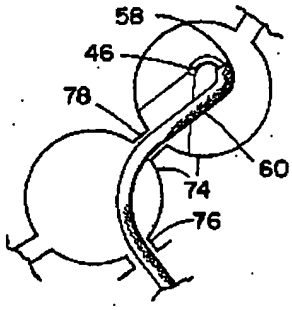


FIG. 19.



Note that claimed inventions are very different from D'Amelio et al. D'Amelio et al. is indifferent to the shapes formed by the apparatus since the D'Amelio device has direct information as to the direction in which the device is pointing. (The entire purpose of D'Amelio et al. is to point an optical inspection apparatus toward the area of interest.)

Turning to the claims, claim 10 requires, inter alia, a catheter tube with a distal end portion fixed in a first curve (that defines a first plane), and fixing the distal end portion of the inner medical element in a second curve such that the distal end of the inner medical element is disposed **substantially out of the first plane** for a period of time sufficient to permit medical use of at least one of the catheter tube or the inner medical element.

As can be seen from the drawings in D'Amelio et al., there are first and second curves as defined in claim 10 only when one is attempting to look back at the entry point into the jet engine can. This is shown in Fig. 19. (Compare Figs. 13-16 in which the inner element is always straight). With respect to Fig. 19, D'Amelio et al. expressly teaches that "objective assembly 46 **must articulate in the same plane** as the guide member 36." Col. 8, lines 37-39. ("Guide member 36" referred to in this passage includes "tubular elongated flexible member 60" shown in Fig. 19—see col. 6, lines 5-8.) D'Amelio et al., therefore, teach directly away from the invention claimed in claim 10. D'Amelio et al. not only teaches it—it demands it, stating that the inner assembly "must" articulate in the same plane as the outer assembly. For all these reasons, the rejection over D'Amelio et al. is baseless. Costella fails to add anything to the rejection of this claim. A combination of D'Amelio et al. and Costella as proposed by the Examiner has to have the feature that D'Amelio et al. says "must" be present—articulation of two

curves in the same plane, rather than in two different planes. In fact, no combination of references with D'Amelio et al. can read on claim 10 given the express teaching of D'Amelio et al. on this fundamental feature of the claim. Claim 10 is allowable for all these reasons.

Claims 11 through 16 depend from claim 10 and are allowable therewith. In addition, claim 11 requires fixing the inner medical element rotationally with respect to the catheter tube. As described above in the discussion of D'Amelio et al., D'Amelio et al. does not provide for rotational fixing. In fact, that would be the very antithesis of how D'Amelio et al. works. D'Amelio et al. provides for longitudinal fixing, but not rotational fixing. Claim 11 is allowable for this reason as well.

Claim 15 specifies that the second curve defines a second plane and that the first plane is fixed at an angle of approximately ninety degrees with respect to the second plane. As discussed above, D'Amelio et al. requires that there be no angle between the plane of the inner element and the plane of the outer element. Certainly, the 90° angle specified in claim 15 is neither disclosed nor taught by these references. Claim 15 is allowable for these reasons as well.

Claim 19 is an independent claim that requires a catheter tube having a distal end portion fixed in a first curve such that the distal end portion of the catheter tube defines a first plane, and an inner medical element in the catheter tube. The claim further specifies forming the combination catheter into a shape in which the distal end of the combination catheter is disposed substantially out of the first plane for a period of time sufficient to permit medical use of at least one of the catheter tube or the inner medical element. As discussed above in connection with claim 10, these references do not show—and in fact

teach away from—the method in which the distal end of the combination catheter is disposed "substantially out of the first plane." Claim 19 is, therefore, allowable for exactly the same reasons as claim 10.

Claims 20-22, 24 and 26 all relate back to claim 19 and are allowable for the same reasons as that claim. Claim 24, in addition, requires proximally fixing the distal end of the combination catheter substantially out of the first plane. Since these references teach away from forming such an out-of-plane shape, they also teach away from fixing the combination catheter in that shape. Claim 26 also provides for proximally fixing the inner medical element against translation and rotation with respect to the catheter tube. As discussed above, D'Amelio et al. fixes against translation but not rotation. In fact fixation against rotation is undesirable in D'Amelio et al. because of how the device is used. Any combination of references with D'Amelio et al., therefore, cannot include the required proximal fixing against rotation of claim 26. Claims 24 and 26 are allowable for these reasons as well.

Claim 28 is another independent claim. It includes the out-of-plane feature discussed above in connection with claims 10 and 19, and the proximal fixing against rotation (and translation) feature discussed above in connection with claim 26. It is allowable over these references, therefore, for the same reasons as both those claims.

Claim 29 is an independent claim that requires not only the forming of a first out-of-plane configuration, but also a second. It also requires proximal fixation against rotation (and translation) during those times when the distal end portion of the combination catheter is in the first out-of-plane configuration, and during those times when it is in the second out-of-plane configuration. These references do not teach a

single out-of-plane configuration, much less two. Nor does this combination teach the requisite proximal fixing against rotation. Claim 29 is allowable for all these reasons.

Claims 31, 33 and 34 depend from claim 10 and are allowable therewith. Claim 31 further requires that the second curve is disposed substantially out of the first plane by rotating the inner medical element with respect to the catheter tube. D'Amelio et al., as explained above, teaches away form making such an out-of-plane shape, so it certainly also teaches away from rotating the inner medical element with respect to the catheter tube in order to make such a (prohibited) shape. Claim 31 is also allowable for these reasons. Claim 33 provides that the fixing step includes proximally fixing the distal end of the combination catheter substantially out of the first plane. This feature, as discussed above in connection with claim 11 is absent from this art. Claim 34 specifies that the inner medical element is proximally fixed against translation and rotation with respect to the catheter tube. As discussed above, this feature is also absent from this combination. Claim 34 is also allowable for this reason.

Claim 32 depends from claim 19 and is allowable for the same reasons as that claim.

The Forester et al reference is cited for the disclosure of an inner member positioned in an out of plane configuration for viewing the gall bladder. This appears to be another example of ignoring the claim requirement that the "distal **end** portion" have an out of plane configuration. It appears from Forester that the distal end portion in all the examples is planar. This reference adds nothing. Even if it were relevant, how could it logically be combined with a reference (D'Amelio et al) that expressly teaches not to go out of plane?

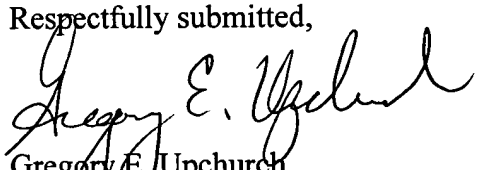
The Patel reference is not responded to herein, since the Examiner has apparently cited it but not applied it.

CONCLUSION

For all the reasons set forth above, claims 10-16, 19-22, 24, 26, 28, 29, and 31-34 are allowable over this art. Favorable reconsideration and a Notice of Allowance are solicited.

The Office is hereby authorized to charge deposit account #08-3460 for any additional fees required.

Respectfully submitted,



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